

JAN - 9 1997

**Summary Basis of Substantial Equivalence.
510 (k) Summary**

K964620

PanoGauze™ Non-Woven Hydrogel Dressing is substantially equivalent in design, composition and function to the Carrington Laboratories, Inc. CarraGauze™ Carrasyn™ Gel Wound Dressing Saturated Pad, 510(k) #K915001, authorized for marketing January 31, 1992.

This is a Class II, (21 CFR §878.4022) Hydrogel Wound & Burn Dressing. There are no established performance standards. PanoGauze™ Non-Woven Hydrogel Dressing, like the CarraGauze™ Carrasyn™ Gel Wound Dressing Saturated Pad, is intended to provide a moist packing/healing environment which helps to prevent wound desiccation. Both are absorbent pads saturated with water based hydrogels packaged in sterile single-use poly/Mylar-laminate pouches.

In regards to safety, several studies were conducted by an independent testing laboratory that demonstrate the following with regard to PanoGauze™ Non-Woven Hydrogel Dressing:

- Met the USP requirements for systemic toxicity,
- Meets USP requirements for cytotoxicity,
- Is not considered a primary irritant to the skin per the guidelines of the Federal Hazardous Substances Act (FHSA) Regulations, 16 CFR 1500. In fact, no irritation was observed,
- Showed no evidence of causing delayed dermal contact sensitization.

In summary, PanoGauze™ Non-Woven Hydrogel Dressing can be determined to be substantially equivalent to CarraGauze™ Carrasyn™ Gel Wound Dressing Saturated Pad on the basis that it maintains a moist environment in the wound bed, does not introduce microbial contamination, and is safe to use - as established by negative results when tested for toxicity.